UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 17, 2018

FibroGen, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-36740	77-0357827
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
(Address of principal executive offices, including zip code)

(415) 978-1200
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events

On December 17, 2018, FibroGen, Inc. announced that its subsidiary, FibroGen (China) Medical Technology Development Co., Ltd., received marketing authorization from the National Medical Products Administration in China for roxadustat, a first-in-class hypoxia-inducible factor prolyl hydroxylase inhibitor, for the treatment of anemia caused by chronic kidney disease in patients on dialysis.

A copy of such press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "FibroGen Announces Approval of Roxadustat in China for the Treatment of Anemia in Chronic Kidney Disease Patients on Dialysis " dated December 17, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

FIBROGEN, INC.

Dated: December 17, 2018

By: /s/ Michael Lowenstein
Michael Lowenstein
Chief Legal Officer

Exhibit 99.1

FibroGen Announces Approval of Roxadustat in China for the Treatment of Anemia in Chronic Kidney Disease Patients on Dialysis

China is the First Country to Approve Roxadustat

First-in-Class Roxadustat Offers a New, Effective Oral Treatment

SAN FRANCISCO, December 17, 2018 – FibroGen, Inc. (NASDAQ:FGEN) today announced that FibroGen (China) Medical Technology Development Co., Ltd. (FibroGen China) has received marketing authorization from the National Medical Products Administration (NMPA) for roxadustat, a first-in-class hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) for the treatment of patients with anemia caused by chronic kidney disease (CKD) in patients who are dialysis-dependent (DD). The medicine can be prescribed to patients who use hemodialysis or peritoneal dialysis.

Anemia caused by CKD is associated with cardiovascular disease, hospitalization, cognitive impairment, and reduced quality of life, and has been shown consistently to increase the mortality risk in patients with CKD.[1] Anemia becomes increasingly common among individuals with CKD as their disease progresses, affecting nearly all patients at the dialysis-eligible stage.[1]

Thomas B. Neff, Chief Executive Officer, FibroGen, said: “We believe roxadustat will make a significant difference for patients in China by addressing a substantial unmet medical need in the treatment of anemia associated with chronic kidney disease. This is an exciting milestone, as we are realizing our decade-long commitment to bringing innovative medicine to people in China. We look forward to bringing roxadustat to patients worldwide.”

Chris Chung, Managing Director, FibroGen China, said: “We are grateful to the patients and physicians in China who participated in our clinical studies. Almost ten years ago, FibroGen made the decision to develop roxadustat, a first-in-class investigational candidate, in China as a Domestic Class 1 Innovative Drug. It arose out of a commitment to give Chinese patients accelerated access to critically needed innovative medicines.”

Roxadustat (China Approved Drug Name: 罗沙司他; Chinese brand name: 爱瑞卓®) is the first approved oral HIF-PHI medicine. This approval is supported by an open-label, active-control 26-week Phase 3 trial in DD-CKD patients with anemia who were previously treated with various forms of locally manufactured injectable recombinant erythropoietin products. In the trial, these DD-CKD patients were then randomized to receive either roxadustat or ESPO® (利血宝®) brand epoetin alfa, manufactured and marketed by Kyowa Hakko Kirin.

FibroGen China has also completed a roxadustat China Phase 3 placebo-controlled trial in non-dialysis-dependent (NDD) CKD patients. The addition of NDD patients to the label is expected once regulatory inspections of the clinical trial sites by the NMPA are completed.

Anemia commonly develops in association with CKD. Based on a large-scale cross-sectional survey performed between September 2009 and September 2010 and published in the *Lancet*, there are an estimated 120 million CKD patients in China, including estimated 0.5 million patients on dialysis who may be suffering from anemia, a number that is increasing significantly.[2,3]

AstraZeneca and FibroGen China are collaborating on the development and commercialization of roxadustat in China. FibroGen China, based in Beijing, is a subsidiary of FibroGen, Inc. that sponsored the development and registration of roxadustat as a Domestic Class 1 Innovative Drug. FibroGen China conducted the China Phase 3 clinical trials and submitted the New Drug Application for registration of roxadustat to the Chinese regulatory authorities. Following this approval, AstraZeneca will manage commercialization activities in China, and FibroGen China will manage commercial manufacturing and medical affairs as well as continued clinical development and regulatory affairs. AstraZeneca and FibroGen expect to launch roxadustat in China in the second half of 2019.

About Roxadustat

Roxadustat (FG-4592), discovered by FibroGen, is a first-in-class, orally administered small molecule currently approved in China for the treatment of patients with anemia from CKD on dialysis. Roxadustat is a HIF-PHI that promotes erythropoiesis through increasing endogenous production of erythropoietin, improving iron regulation, and overcoming the negative impact of inflammation on hemoglobin syntheses and red blood cell production by downregulating hepcidin. Administration of roxadustat has been shown to induce coordinated erythropoiesis, increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of CKD patients, including in the presence of inflammation and without a need for supplemental intravenous iron. Roxadustat was well tolerated in the China Phase 3 studies. The adverse events observed were consistent with underlying diseases in patients with CKD.

FibroGen, the originator, and AstraZeneca are collaborating on the development and commercialization of roxadustat for the treatment of anemia in the U.S., China, and other markets in the Americas, Australia, New Zealand and Southeast Asia. FibroGen and Astellas Pharma Inc. and FibroGen are collaborating on the development and commercialization of roxadustat for the treatment of anemia in territories including Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.

About Anemia Associated with CKD in China

Anemia commonly develops in association with chronic kidney disease and is linked to significant morbidity and mortality in both the dialysis and non-dialysis populations. Although CKD may occur at any age, it is more common in aging populations, and its prevalence is increasing. CKD can be both a cause and a consequence of cardiovascular disease and is a critical healthcare issue. There is no treatment available that is curative, or has the ability to stop kidney deterioration.

About FibroGen

FibroGen, Inc., headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China, is a leading biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in hypoxia-inducible factor (HIF), connective tissue growth factor (CTGF) biology, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat, the company's most advanced product candidate, is an oral small molecule inhibitor of HIF prolyl hydroxylase activity, completing worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), with a New Drug Application (NDA) now approved by the

National Medical Products Administration (NMPA) in China. Our partner Astellas submitted a NDA for the treatment of anemia in CKD patients on dialysis in Japan and currently under review by the Pharmaceuticals and Medical Devices Agency (PMDA). Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes (MDS). Pamrevlumab, an anti-CTGF human monoclonal antibody, is advancing towards Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). FibroGen is also developing a biosynthetic cornea in China. For more information, please visit www.fibrogen.com.

Forward-Looking Statements

This release contains forward-looking statements regarding our strategy, future plans and prospects, including statements regarding the development of the company's product candidates pamrevlumab and roxadustat, the potential safety and efficacy profile of our product candidates, and our clinical, regulatory plans, and those of our partners. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "will", "should," "on track," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of our various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, and our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018 filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press release, except as required by law.

爱瑞卓® is a registered trademark of FibroGen, Inc.

References

1. Babitt JL, Lin HY. Mechanisms of Anemia in CKD. J Am Soc Nephrol (2012); 23:1631-1634.
2. Zhang L, Wang F, Wang L, et al. Prevalence of chronic kidney disease in China: a cross-sectional survey. *Lancet* 2012; 379: 815–22.
3. China National Renal Data System (CNRDS), 2016.

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Contact

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